

**PATENT COOPERATION TREATY**  
**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
 (Chapter I of the Patent Cooperation Treaty)  
 (PCT Rule 44bis)

Applicant's or agent's file reference <b>S11530WO01</b>	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. <b>PCT/JP2005/005077</b>	International filing date ( <i>day/month/year</i> ) <b>15 March 2005 (15.03.2005)</b>	Priority date ( <i>day/month/year</i> ) <b>15 March 2004 (15.03.2004)</b>	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant <b>SUMITOMO CHEMICAL COMPANY, LIMITED</b>			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report <b>14 November 2006 (14.11.2006)</b>	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Authorized officer  <b>Masashi Honda</b>  e-mail: pt08@wipo.int

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

*TRANSLATION*  
**PCT**

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)	<b>14.06.2005</b>
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Applicant's or agent's file reference <b>S11530W001</b>	<b>FOR FURTHER ACTION</b> See paragraph 2 below
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International application No. <b>PCT/JP2005/005077</b>	International filing date (day/month/year) <b>15.03.2005</b>	Priority date (day/month/year) <b>15.03.2004</b>
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International Patent Classification (IPC) or both national classification and IPC

**C12N15/11, A61K45/00, A61P25/18, 25/22, 25/24, C12N1/15, 1/19,  
1/21, 5/10, C12Q1/02, 1/68, G01N33/15, 33/50**

Applicant

**SUMITOMO CHEMICAL COMPANY, LIMITED**

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- a sequence listing  
 table(s) related to the sequence listing

b. format of material

- in written format  
 in computer readable form

c. time of filing/furnishing

- contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application  
 claims Nos. 14

because:

- the said international application, or the said claims Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 14 are so unclear that no meaningful opinion could be formed (*specify*):

[See the Supplemental Box]

- the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for said claims Nos. \_\_\_\_\_
- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |   |
|----------------------------|---|
| the written form           | <input type="checkbox"/> has not been furnished<br><input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished<br><input type="checkbox"/> does not comply with the standard |
- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- See Supplemental Box for further details.

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<b>Box No. V</b>	<b>Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b>
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**1. Statement**

Novelty (N)	Claims	1-13	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

**2. Citations and explanations:**

Document 1: EP 1382613 A1 (Sumitomo Chemical Co., Ltd.),  
 21 January 2004 & JP 2004-350672 A & CA  
 2432968 A

Claims 1-13

The inventions set forth in claims 1-13 do not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 discloses a nucleotide sequence for a gene coding Gml, which is an  $\alpha$  subunit of a G protein trimer (see claim 7 and SEQ ID NO: 27).

In the technical field to which the inventions in the present application pertain, clarifying the type of transcription regulation applying to an isolated gene is a commonly known problem, and using the 5' region of the gene as a probe to isolate from a suitable genome library polynucleotides which are present in a region upstream from said gene and have promoter activity, constructing plasmids with a reporter gene attached to a resulting promoter, and using cells genetically modified by introducing said plasmid to screen substances which are able to regulate transcription via the promoter in question, using quantitative changes in the expression of

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Box No. V      **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

the reporter gene as an indicator, are known techniques for addressing the aforementioned problem (if necessary, see JP 2002-034575 A (Shiseido Co., Ltd.), 5 February 2002 & WO 2002/010376 A1 & EP 1306432 A1, cited in the international search report, etc.). Screening of substances which act as transcription regulating factors by binding to the promoter, and purifying such compounds, are also known techniques.

Given this a person skilled in the art could easily conceive of using the aforementioned known techniques in order to clarify the type of transcription regulation applying to the Gml gene disclosed in document 1, and derive the inventions disclosed in claims 1-13.

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: III.

Since the nature of specific compounds falling within the scope of "compounds having the capacity to regulate signal transmission via a promoter of the gene coding the G protein trimer  $\alpha$  subunit Gm1, obtained by a screening method according to claim 9 or 11" in claim 14, and the nature of compounds excluded therefrom are entirely unclear, claim 14 is exceedingly imprecise. Therefore, no opinion can be expressed as to the novelty, inventive step or industrial applicability of the invention set forth in claim 14.